

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 146-154 are pending after entry of the amendments set forth herein.

Claim 151 are amended to insert the correct ATCC deposit number, and the specification amended to insert reference to the deposit.

Applicants respectfully request entry of the amendments made herein.

No new matter has been added.

**Amendment to Specification and Claim 151**

Applicants recently discovered that the ATCC Deposit number referred to in claim 151 was in error. Claim 151 is amended to recite the correct ATCC Deposit number, and the specification amended to refer to this deposit.

Applicants submit herewith a copy of the ATCC Deposit Certificate (Exhibit A), showing that the library ES10 (referred to internally at Chiron as Chiron Master Culture Collection (CMCC) No. 4883) was deposited on January 13, 1999 and assigned ATCC Deposit no. 207032.

The ES10 library (CMMC No. 4883) contained the clone M00001448D:C09 referred to in claim 151, as evidenced by the "Plasmid Strain Deposit Form" (Exhibit B; see particularly spreadsheet on last page). The clone M00001448D:C09 was specifically referred to in Table 1 of the specification as originally filed (see entry for SEQ ID NO:253), and appeared in at least the parent PCT application, filed January 28, 1999.

I hereby affirm, on behalf of applicants, that (a) all restrictions on the availability to the public of the biological material referred to herein will be irrevocably removed upon issuance of a United States patent of which such biological materials are the subject (except restrictions allowed 37 CFR §1.808 requiring the request for the deposit to be in the format specified in 37 CFR §1.808(b)); (b) the biological material will be maintained for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited biological materials was received by the ATCC and, in any case, for a period of at least thirty (30) years after the date of the deposit; (c) should the deposited biological material become non-viable, it

will be replaced by the Assignee; and (d) access to the biological materials will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

**Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number IRVN-009CON.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: August 14, 2003

By: Carol L. Francis  
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Registration No. 36,513

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Enclosures: ATCC Deposit Certificate (Exhibit A)  
Plasmid Strain Deposit Form, Chiron Master Culture Collection (Exhibit B)

# ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE  
INTERNATIONAL FORM**

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2**

To: (Name and Address of Depositor or Attorney)

Chiron  
Attn: Karen Van Note  
4560 Horton Street  
Emeryville, CA 94608

Deposited on Behalf of: Chiron (Ref. 1480.001)

Identification Reference by Depositor: ATCC Designation

Plasmid in <i>E. coli</i> Library ES6 CMCC#4879	207028
Plasmid in <i>E. coli</i> Library ES7 CMCC#4880	207029
Plasmid in <i>E. coli</i> Library ES8 CMCC#4881	207030
Plasmid in <i>E. coli</i> Library ES9 CMCC#4882	207031
Plasmid in <i>E. coli</i> Library ES10 CMCC#4883	207032

/The deposits were accompanied by: ☐ a scientific description ☒ a proposed taxonomic description indicated above. The deposits were received December 22, 1998 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested January 13, 1999. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:



Barbara M. Hailey, Administrator, Patent Depository

Date: January 13, 1999

cc: Ling-Fong Chung  
cc: Jane Potter

EXHIBIT A

Vial #10

PLASMID STRAIN DEPOSIT FORM  
Chiron Master Culture Collection

CMCC 4883

Please type or print.

Plasmid Name Library ES10 PCS2+ Size (kbp): Plasmid 3.9 Insert: 500-2000 bp

Host Name (circle): E. coli Bacillus, Other: \_\_\_\_\_

Host Strain & Genotype: check if listed, or give name, and genotype: \_\_\_\_\_ DH5alpha/ \_\_\_\_\_ MM294/  
\_\_\_\_\_ MM294-1/ \_\_\_\_\_ DG95/ \_\_\_\_\_ DG95N/ \_\_\_\_\_ DG116N/ \_\_\_\_\_ CS412/

Other (specify genotype): XL2-blue mrf'

Source of this culture:

☒ Developed Inhouse

☐ Other:

Culture Collection \_\_\_\_\_

Other Company \_\_\_\_\_

Individual \_\_\_\_\_

Former stock/culture numbers/synonyms: \_\_\_\_\_

Does any non-Chiron party have ownership rights to this plasmid?

No. To my knowledge all rights belong to Chiron

☐ No. Culture is in public domain

☐ Uncertain (explain): \_\_\_\_\_

☒ Yes. If yes, to whom do rights belong? Explain and attach documents and correspondence if available: Subject to Hyseq collaboration agreement

What containment level is required for this culture per the 1983 NIH Guidelines for recombinant molecules? Please circle P1 P2 P3 P4

Is this strain being considered for a Chiron patent? yes

Give case number and attorney, if known 1480.100 Jane Potter

The information requested below is necessary for proper characterization of the culture and for our scientific database. Please be as complete and detailed as possible.

Indicate plasmid replicon(s) and designate original parent plasmid(s) from which the origin(s) was/were derived (e.g. E. coli \_\_\_\_\_):

E. coli / Bacillus / Yeast / Mammalian /

Other \_\_\_\_\_

Plasmid Markers (indicate resistance in ug/mL) 100 (AP) TC/ KM/ CM/

Colicin/ Lac/ Others: \_\_\_\_\_

Primary utility: Cloning/ Expression/ Probe: \_\_\_\_\_ Library

Other: \_\_\_\_\_

EXHIBIT B

•Gene Cloned (be specific): Novel genes from colon cancer cell lines  
(see attached lists. mixture of 7 clones)

•Regulatory elements: Promoter:      / Terminator:      / RBS:      /

Par:      / Other:     

•Insert Selection: Inactivation:      / Activation:       
     / Other:     

•Restrictions Sites:  
To remove insert EcoRI / XhoI  
Other unique sites of interest:     

•Is there DNA sequence information available? No / X Yes/ Please attach sequence.

•Restriction map? A map, even if preliminary MUST be attached. If unavailable please explain     

•Notebook References: 10860, 11494

Literature Citations:     

Additional Features or Comments:     

•Growth Conditions for this Culture:  
Agar/broth TB Optimal pH      Optimal temp 37°C

Special Requirements None

Handling Restrictions (e.g. sensitivities, pathogenicity, restricted usage): None

Researcher/Depositor Michael Innis / Beth Scott Date 12/11/98

Dept. Code 303 Proj. Code 565 Bldg 4.4 Ext 8243

Dept Director/Project Manager Signature M. Innis

\*\*\*\*\*CMCC USE\*\*\*\*\*

Processed by:      Date:     

Pre-freeze Date:      Post-freeze Date:      DNA Characterization:     

Inventory Card      Card Catalog      Database     

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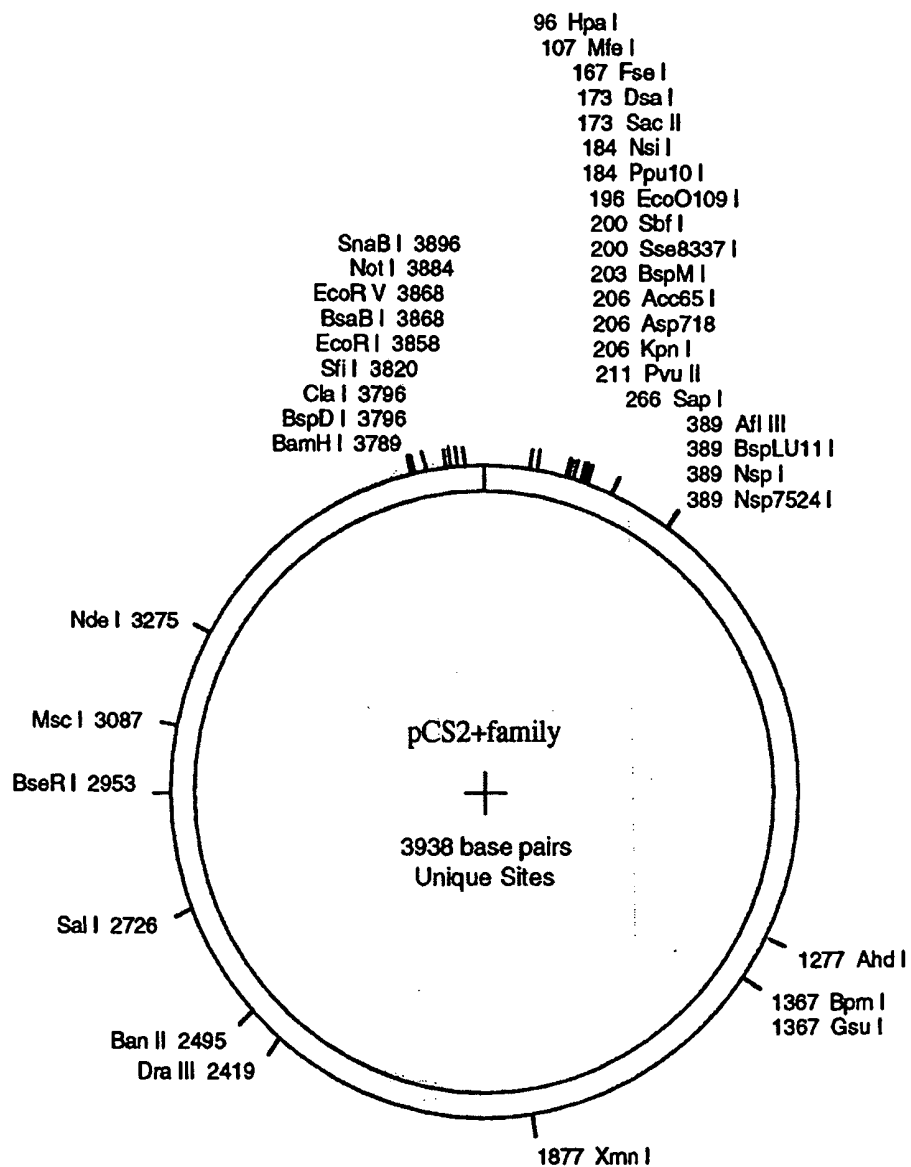
Patent Deposit: Date      Accession#      Case#     

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Documentation Notes

pCS2+family -> Graphic Map

DNA sequence 3938 b.p. AAACCACAAC TA ... ATGAGTTTGGAC circular



Tube Number	Date Pooled	Clone Name	Cluster ID	Sequence Name
10	12/8/98	M00001358C:C06	1	0 RTA00000177AF.o.4.3
10	12/8/98	M00001388D:G05	2 5832	80.F6.sp6:130273.Seq
10	12/8/98	M00001388D:G05	2 5832	RTA00000178AF.o.23.1
10	12/8/98	M00001394A:F01	3 6583	RTA00000179AF.d.13.1
10	12/8/98	M00001394A:F01	3 6583	172.B8.sp6:133896.Seq
10	12/8/98	M00001394A:F01	3 6583	80.H6.sp6:130297.Seq
10	12/8/98	M00001429A:H04	4 2797	RTA00000180AF.i.19.1
10	12/8/98	M00001447A:G03	5 10717	RTA00000181AF.d.10.1
10	12/8/98	M00001448D:C09	6 8	80.H10.sp6:130301.Seq
10	12/8/98	M00001448D:C09	6 8	RTA00000181AF.e.17.1
10	12/8/98	M00001448D:C09	6 8	100.B11.sp6:131444.Seq
10	12/8/98	M00001454D:G03	7 689	RTA00000181AR.i.22.1